Environmental Management Quality Assurance Checklist

1. Organization Evaluated	2. ☐ Audit ☐ Surveillance	3. Prepared by: _____ Signature: _____ Date: _____
4. Activity Evaluated:		
5. Controlled Document: EM-QA-001, Revision 1, *EM Quality Assurance Program*	6. Dates of Evaluation:	

7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
1-1	**Criterion 1 – Management/Program** Verify that an organizational structure, functional responsibilities, levels of authority and interfaces are established for those managing, performing and assessing work. (EM QAP-7.1.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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1-2	Verify that the personnel responsible for assuring that an appropriate quality assurance program has been established, and the personnel, responsible for verifying activities affecting quality, have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to safety function considerations. (NQA-1-2008/2009a, Requirement 1, Part 200)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
1-3	Verify that management processes are established, including planning, scheduling and providing resources for work. (EM QAP 7.1.1, 7.1.2) Note: The QAP/QIP shall identify the need to establish the Quality Program and begin its implementation at the earliest time consistent with the schedule for accomplishing the activities. (NQA-1, Requirement 1, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
1-4	Verify that the activities and items are identified and provide control over activities affecting quality to an extent consistent with their importance. Verify that monitoring activities against acceptance criteria in a manner are implemented sufficient to provide assurance that the activities affecting quality are performed satisfactorily. (NQA-1, Requirement 1, Section 100) Verify that QA processes and procedures for accomplishing EM mission-related work are established and implemented in a controlled manner. (EM QAP 7.1.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
2-1	**Criterion 2 – Management/Personnel Training and Qualification** Verify the methodology for establishing requirements to train, indoctrinate, and qualify personnel assigned to perform EM mission-related work. (EM QAP 7.2.1, 7.2.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
2-2	Verify that initial and continuing training is provided to employees to develop new skills, maintain or improve job performance, and enhance existing skills. Verify that managers ensure that personnel are fully qualified for their positions. (EM QAP 7.2.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
2-3	Verify that qualifications for specific job categories are based on requirements established by the organization's personnel management, DOE directives, other requirement documents, or management. (EM QAP 7.2.1)	**Personnel Contacted:** • **Documents Reviewed:** •	

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		Discussion:	
2-4	Verify that specialized design, engineering, construction, and operational training include formal and informal training, education, and developmental and other learning assignments. (EM QAP 7.2.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
2-5	Verify the process for training, qualifying, and certifying personnel performing inspections or tests; software QA per Attachment G of EM-QA-001; and suspect/counterfeit item prevention per Attachment F of EM-QA-001. (EM QAP 7.2.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
2-6	Verify that personnel are indoctrinated, trained, qualified prior to independently performing QA program work. Verify that personnel that require certification are given proficiency tests with acceptance criteria. (EM QAP 7.2.1, 7.2.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
2-7	Verify that employee-specific training needs are documented and updated as required to ensure competence required by the position is maintained. Verify that continuing training is established and documented to maintain job proficiency. (EM QAP 7.2.1, 7.2.2; DOE O 414.1D, Criterion 2b)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
3-1	**Criterion 3 – Management/Quality Improvement** Verify that a process is established for detecting and preventing conditions adverse to quality. Verify that Corrective Action Programs utilized and are consistent with DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*; DOE O 227.1, *Independent Oversight Program*; and DOE G 414.1-2B, *Quality Assurance Program Guide*. (EM QAP 7.3.1, 7.3.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
3-2	Verify that operational awareness processes are in place to detect, communicate, and prevent quality problems. (EM QAP 7.3.2)	**Personnel Contacted:** • **Documents Reviewed:**	

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		• **Discussion:**	
3-3	Verify that management has established performance goals and standards including metrics that monitor project/program performance. Verify that improvement processes maintained by this management system include Self-Assessment, Independent Oversight, Lessons Learned, Performance Metrics, and Performance Analysis. (EM QAP 7.3.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
3-4	Verify that a process is developed to determine the significance of identified problems/findings. (EM QAP 7.3.1, 7.3.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
3-5	Verify that conditions adverse to quality and significant conditions adverse to quality are documented, tracked, and reported to appropriate levels of management. (EM QAP 7.3.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
3-6	Verify that corrective actions are developed and implemented for problems/findings related to item characteristics, products, process implementation, or services to prevent recurrence. (EM QAP 7.3.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
3-7	In the case of significant conditions adverse to quality, verify that causes of problems are identified, and prevention of recurrence is included as a part of corrective action planning. Verify that management identifies the causes of problems and takes corrective actions to address the problems. Formal root cause analysis should be considered based on the complexity of the identified significant issue. Root causes should be identified and documented using an authoritative methodology for root cause identification and be performed by root cause analysis-trained personnel. [Reference DOE Order 232.2, *Occurrence Reporting and Processing of Operations Information.*]	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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	Verify that an Extent of Condition determination is considered for significant conditions adverse to quality. Verify that proposed corrective actions are evaluated to ensure they will effectively address the underlying QA performance issues. (EM QAP 7.3.1)		
3-8	Verify that completed corrective actions are independently verified for implementation and the verification documented to indicate closure. (EM QAP 7.3.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-1	**Criterion 4 – Management/Documents and Records** Verify that work is performed to current and controlled implementing documents (procedures) and readily available to the users. Verify that work is suspended if it cannot be accomplished as described in controlled implementing documents. (EM QAP 7.4.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-2	Verify that new or revised requirements are analyzed to determine impact on implementing procedures and/or contracts. (EM QAP 7.4.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-3	Verify that a document control system has been established to prepare, review, approve issue, use and revise documents that prescribe processes, specify requirements, or establish design. (EM QAP 7.4.1, 7.4.2) Verify that the preparation, issuance and change of documents that specify quality requirements, or prescribe activities affecting quality such as instructions, procedures, and drawings are controlled to assure correct documents are being employed.	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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	Verify that documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel. (NQA-1-2009, Requirement 6, Section 100)		
4-4	Verify that documents (procedures) address the first phase of the Federal records lifecycle (Creation / Receipt) in which QA records are identified within implementing procedures prior to startup of work. (EM QAP 7.4.1) Verify that QA records are legible, accurate, complete, and traceable to the associated item or activity to which they apply and accurately reflect the work accomplished or information required. (NQA-1-2009, Requirement 17, Part 200) Verify that records are considered valid when stamped, initialed, or signed and dated by authorized personnel or authenticated. (EM QAP 7.4.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-5	Verify that QA records are defined and classified as lifetime or nonpermanent, retention times specified, and the conditions for disposal are met. Verify that lifetime records are required to be maintained by or for the Owner for the life of the particular item while it is installed in the plant or stored for future use. (NQA-1-2009, Requirement 17, Part 401)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-6	Verify that a receipt control system for QA records is established. (EM QAP 7.4.2). Verify that the designee is responsible for organizing and implementing receipt controls for permanent and temporary storage. (EM QAP 7.4.2; NQA-1-2009, Requirement 17, Part 500) Verify that there are predetermined storage facilities for storing, preserving and maintaining QA records including active records storage in accordance with both NQA-1 and the National Archives and Records Administration (NARA), including the Federal Records Management Program. (EM QAP 7.4.1, 7.4.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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	Verify that access to the processing, storage, and retrieval of records is limited to authorized personnel. (NQA-1-2009, Requirement 17, Part 601)		
4-7	Verify that storage methods preclude deterioration of QA records, QA records are filed appropriately for the QA record medium being stored. (EM QAP 7.4.2) Verify that provisions are made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage. (NQA-1-2009, Requirement 17, Part 601)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-8	Verify that there are implementing documents that identify means for replacement, restoration, or substitution of lost or damaged QA records. (EM QAP 7.4.2) Verify that methods for record changes are documented. (NQA-1-2009, Requirement 17, Part 800)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-9	Verify that quality affecting activity is described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. Verify that the need for, and level of detail in, written procedures or instructions are determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience). (NQA-1-2009, Requirement 5, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-10	Verify that minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents same review and approval as the original documents. Verify that, to avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision are clearly delineated. (NQA-1-2009, Requirement 6, Part 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-11	Verify that the control of quality assurance records is established consistently with the schedule for accomplishing work activities. (NQA-1-2009, Requirement 17, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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4-12	Verify that record control requirements and responsibilities for these activities are documented. (NQA-1-2009, Requirement 17, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-13	Verify that electronic documents are authenticated with comparable information as in paragraph 300(a), as appropriate (1) with identification on the media; or (2) with authentication information contained within or linked to the document itself. (NQA-1-2009, Requirement 17, Part 300)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-14	There are two equally satisfactory methods of providing storage, single or dual. Single storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire-rating. Verify that the design and construction of a single storage facility, vault room, or container are reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization. (NQA-1-2009, Requirement 17, Part 602)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-15	Verify that dual facilities, containers, or a combination thereof are at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. (Facilities used for dual storage are not required to satisfy the requirements of paragraph 602.1, but shall meet the requirements of paragraph 601.) (NQA-1-2009, Requirement 17, Part 602)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-16	Verify that when temporary storage of records (such as for processing, review, or use) is required, the storage facility or container provide a one-hour fire rating, unless dual storage requirements of paragraph 602.2 are met. (NQA-1-2009, Requirement 17, Part 603)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-17	Verify that record retention periods are documented.	**Personnel Contacted:**	

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	(NQA-1-2009, Requirement 17, Part 700)	• **Documents Reviewed:** • **Discussion:**	
4-18	Verify that records are maintained for their retention period. (NQA-1-2009, Requirement 17, Part 700)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-19	Verify that record controls provide for retrievability within planned retrieval times based upon the record type or content. (NQA-1-2009, Requirement 17, Part 800)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-20	Verify that provisions are established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period. (NQA-1-2009, Requirement 17, Part 800)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-21	Verify that provisions are made to ensure that the records remain retrievable after hardware, software, or technology changes. (NQA-1-2009, Requirement 17, Part 800)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
4-22	Verify that provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage: (1) duplication or transfer is appropriately authorized (2) record content, legibility, and retrievability are maintained. (NQA-1-2009, Requirement 17, Part 800)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
5-1	**Criterion 5 – Performance/Work Processes**	**Personnel Contacted:** • **Documents Reviewed:**	

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	Verify that work processes are defined, consistent with technical standards, administrative controls and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures. (EM QAP 7.5.1)	• **Discussion:**	
5-2	Verify that requirements and process properly identify and control items to ensure their proper use. (EM QAP 7.5.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
5-3	Verify that requirements and process are identified to maintain items to prevent their damage, loss or deterioration. (EM QAP 7.5.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
5-4	Verify that handling, storage, cleaning, packaging, shipping, and preservation of items are conducted in accordance with established work and inspection implementing documents, shipping instructions or other specified documents. (EM QAP 7.5.1, 7.5.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
5-5	Verify that the status of required inspection and tests of items is indicated when necessary to preclude inadvertent bypassing of such inspections and tests. Verify that the status of inspections and tests is identified either on the items or in documents traceable to the items. (EM QAP 7.5.1, 7.5.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
5-6	Verify that requirements and process are defined to calibrate, maintain and use equipment used for process monitoring or data collection. (EM QAP 7.5.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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6-1	**Criterion 6 - Performance/Design** Verify integration of QA during design. Verify the development and use of a Code of Record during design. (EM QAP 7.6.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
6-2	Verify that designs are based on appropriate national standards and industry recognized engineering practices. (EM QAP 7.6.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
6-3	Verify that applicable design bases are incorporated. (EM QAP 7.6.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
6-4	Verify that design interfaces are identified and controlled. (EM QAP 7.6.1) Verify that design interfaces include the integration of activities of organizations that can affect the approved configuration. (NQA-1-2008/2009a, Requirement 2, Part 600) Verify that interface controls include the assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces. Verify that design information across interfaces identify the status of the design information or document provided and identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, verify that the transmittal is confirmed promptly by a controlled document.	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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	(NQA-1-2008/2009a, Requirement 2, Part 700)		
6-5	Verify that applicable design inputs are controlled by those responsible for the design and that: • Design inputs are identified and documented, and their selection reviewed and approved by those responsible for the design. • Design inputs are specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent a consistent basis for making design decisions, accomplishing design verification measures, and evaluation design changes. (NQA-1-2008/2009a, Requirement 3, Part 200)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
6-6	Verify that the responsible design organization prescribe and document the design activities to the level of detail necessary to permit the design process to be implemented in a correct manner and to permit verification that the design meets requirements. Verify that the design process is controlled according to these requirements: • Design work is prescribed and documented on a timely basis to the level of detail necessary to permit the design process to be carried out in a correct manner and verification that the design meets requirements. • Design documents support facility design, construction, and operation. • Appropriate quality standards are identified and documented, and their selection reviewed and approved. • Design methods, materials, parts, equipment, and processes essential to the function of the items are selected and reviewed for suitability of application. • Applicable information derived from experience are made available to design personnel. Verify that the final design is related to the design input by documentation in sufficient detail to permit design verification; specify required inspections and tests and include or reference appropriate acceptance criteria; and identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics meet the requirements of NQA-1-2009a, Part II, Subpart 12, “Quality Assurance Requirements for Commercial Grade Items and Services.”	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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	(NQA-1-2008/2009a, Requirement 3, Part 300)		
6-7	Verify that design analysis meet the following requirements: • Design analyses are sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. • Computer program acceptability, to the extent required, is pre-verified or the results verified with the design analysis for each application. • The computer program is verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. • The encoded mathematical model is shown to produce a valid solution to the physical problem associated with the particular application. • Design analyses are documented and include: objective of analyses; design inputs and sources; results of literature searches or other background data; assumptions and indication of those assumptions that must be verified as the design proceeds; identification of any computer calculation including computer type, computer program name and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to specific physical problem; and review and approval. (NQA-1-2008/2009a, Requirement 3, Part 400)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
6-8	Verify that design reviews are implemented by personnel other than those who performed the work. (EM QAP 7.6.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
6-9	Verify that design work is verified before approval and implementation. (EM QAP 7.6.1) Verify that the design organization identifies and documents the particular design verification method(s) used. The results of the design verification are documented with the identification of the verifier clearly indicated. Verify that the design verification is performed by any competent individual or group other than those who performed the original design but who may be from the same organization.	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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	Verify that the verification may be performed by the originator's supervisor, provided that the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification. Verify that the design verification is performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design is identified and controlled. Verify that the design verification is completed prior to relying upon the component, system, structure, or computer program to perform its function. If the design is modified to resolve verification findings, verify that the modified design is verified prior to release for use. Verify that the extent of the design verification is a function important to safety, design complexity, the degree of standardization, the state of the art, and similarity with previously proved designs. Where the design has been subjected to a verification process, verify that the verification process is not duplicated for identical designs. Verify that the verification is performed using one or combination of the following acceptable methods: design review, alternate calculations, and qualification testing. Verify that design reviews provide assurance that the final design is correct and satisfactory by addressing the following: • Were design inputs correctly selected? • Are assumptions necessary to perform the design activity adequately described and reasonable, where necessary, are the assumptions identified for subsequent re-verifications when detailed design activities are completed? • Were appropriate design methods and computer programs used? • Were the design inputs correctly incorporated into the design? • Is the design output reasonable compared to design inputs?		

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	• Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions? • Have suitable materials, parts, process, and inspection and testing criteria been specified? Verify that alternate calculations use alternate methods to verify correctness of the original calculations or analyses. Review the appropriateness of assumptions, input data used, and the computer program, its associated computer hardware and system software, or other calculation methods. Verify that qualification testing demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Verify that operating modes and environmental conditions are considered in determining the most adverse conditions. Determine that other features of the design are verified by other means where the test is intended to verify only specific design features. Where tests are being performed on models or mockups, verify that scaling laws are established and verified. Verify that results of model test work are subject to error analysis, where applicable, prior to use in the final design. (NQA-1-2008/2009a, Requirement 3, Part 500)		
6-10	Verify that changes to design inputs, final designs, field changes, and temporary and permanent modifications are justified and subject to design control measures commensurate with those applied to the original design. Verify that changes are approved by the same affected groups or organizations that reviewed and approved the original design documents. Where a significant design change is necessary because of an incorrect design, verify that the design process and verification procedure are reviewed and modified as necessary. Verify that procedures implementing configuration management requirements are established and documented at the earliest practical time prior to facility operations, and include responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities, such as operations, design, maintenance, construction, licensing, and procurement. Verify that configuration management requirements include measures to ensure changes that may affect the approved configuration are recognized and processed. Verify that configuration is established and approved at the earliest time practical prior	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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	to initial operation of the facility and maintained for the life of the facility. Verify that configuration include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements and other applicable sources. Verify that documentation identify the design bases and the approved configuration for the approved modes of operation. Verify measures are established and implemented to assure that proposed changes to the configuration are evaluated for their conformance to the design basis. Verify that implementation sequence for approved configuration changes are reviewed to determine that the configuration conforms to the design bases. Verify that approval by the design authority is required prior to implementation of a change to the design bases. Verify that configuration of the facility is documented in drawings, specifications, procedures and other documents which reflect the operational status of the facility. Verify that process utilized to control the current revision and issuance of these documents take into account the use of the document and the need for revision in support of the operation. (NQA-1-2008/2009a, Requirement 3, Part 600)		
6-11	Verify that the requirements of Section 800 are applied to computer software design control processes and activities. Verify that the software design process are documented, approved by the responsible design organization, and controlled. Verify that software design requirements are identified and documented and their selection reviewed and approved. Verify that software design requirements identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.		

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	Verify that the software design is documented and define the computational sequence necessary to meet the software requirements. Documentation include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process, flow, data structures, process structures and the applicable relationships between data structures and process structures. The documentation may be combined with the documentation of the software design requirements, or the computer program listings resulting from implementation of the software design. Verify that software design is translated into computer program(s) using the programming organization's or design organization's programming standards and conventions. Verify that software design verification is performed by competent individuals(s) or group(s) other than those who developed or documented the original design, but may be from the same organization. Verify that results of verification are documented with the identification of the verifier indicated. Verify that verification may be performed by the originator's supervisor, provided that the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification. Verify that results of the verification are documented with the identification of verifier indicated. Verify that software verification methods include one or a combination of design reviews, alternate calculations and tests performed during computer program development: the extent of verification and methods chosen are a function of: • complexity of the software • degree of standardization • similarity with previously proved software • importance to safety Verify that computer program testing is performed and accomplished with NQA-1-2008/2009a Requirement 11. (NQA-1-2008/2009a, Requirement 3, Part 800)		
6-12	Verify that software configuration management includes, but is not limited to, configuration identification, change control, and status control. Verify		

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	that configuration items are maintained under configuration management until the software is retired. Verify that a software baseline is established at the completion of each activity of the software design process. Verify that approved changes created subsequent to a baseline are added to the baseline. Verify that a baseline define the most recently approved software configuration. Verify that a labeling system for configuration is implemented that: • uniquely identifies each configuration item • identifies changes to configuration items by revision • provides the ability to uniquely identify each configuration of the revised software available for use. Verify changes to software are formally documented to include: • description of the change • rationale of the change • identification of affected software baselines. Verify that change is formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Verify that only authorized changes are made to software baselines. Verify that appropriate verification activities are performed for the change. Verify that the change is appropriately reflected in documentation and traceability of the change to the software design requirement is maintained. Verify that appropriate acceptance testing is performed for the change. Verify that status of configuration items resulting from software design is maintained current. Verify that configuration item changes are controlled until they are incorporated into the approved product baseline. Determine that the control includes a process for maintaining the status of changes which are proposed and approved, but not implemented. Verify that the controls provide for notification of this information to affected organizations. (NQA-1-2008/2009a, Requirement 3, Part 800)		
6-13	Verify that design documentation and records include not only final design documents, such as drawings and specifications, and revisions to those		

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	documents, but also documentation which identifies the important steps in the design process, including sources of design inputs that support the final design. (NQA-1-2008/2009a, Requirement 3, Part 900)		
7-1	**Criterion 7 – Performance/Procurement** Verify that procurement documents include the following provisions to ensure quality as applicable to the item (including spare parts and replacements) or service being procured: Statement of the scope of work to be performed; technical and QA program requirements; right of access to supplier facilities and records; Provisions for hold points beyond which work cannot proceed without purchaser authorization; schedule for submittal of documents to purchaser for information, review and approval; reporting of nonconformances dispositioned as use-as-is or repair to the purchaser for approval of the disposition; identification of spare and replacement parts or assemblies, and instructions relative to the performance of special processes; and controls to mitigate procurement and installation of counterfeit or fraudulent items. Verify that changes to procurement documents are subject to the same degree of control as used in the preparation of the original documents. (EM QAP 7.7.1, 7.7.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-2	Verify that the Standard QA Contract language is included in prime contracts and applicable QA requirements are included in subcontracts. (EM QAP 7.7.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-3	Verify that the quality program specify documented procedures for Acquisition Planning, Vendor Surveys, Bid Evaluations, Contractor Oversight, Contract Administration and Source Evaluation and that establish requirements to be met by approved suppliers. (EM QAP 7.7.1) Has responsibility for the oversight of procedural implementation been assigned? Verify that the quality program specify an assigned responsibility for monitoring and oversight of contractor performance with sufficient authority to assure correction of deficiencies. (EM QAP 7.7.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
7-4	Verify that the quality program specify an explicit delegation of procurement authorities to specific employees. . (EM QAP 7.7.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-5	Verify that the quality program specify how the requirements for the procurement of items and services are established, including provisions for Commercial Grade Dedication (CGD) items. Verify the process for procuring commercial grade (CG) items as follows: the item's critical characteristics are specified in approved design and procurement documents; verification of the item's critical characteristics is achieved by application of a dedication process to be performed by a specified dedicating entity; and implementing processes are developed to be consistent with Electric Power Research Institute (EPRI) Guidelines. (EM QAP 7.7.1, NQA-1-2009a Subpart 2.14))	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-6	Verify that the process ensure that items and services procured meet established requirements and perform as specified. (NQA-1-2009a, Requirement 7, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-7	Verify that procurement document changes are managed and controlled at the same level as the original. (EM QAP 7.7.1, 7.7.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-8	Verify that a system is developed to evaluate and select prospective suppliers based on specified criteria. Verify that supplier documentation is managed and controlled. (DOE Order 414.1D, Section 7b)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
7-9	Verify that a system is established for identifying potential suspect/counterfeit items (S/CI) and its prevention as described in Attachment F, Suspect/Counterfeit Items Prevention, of EM-QA-001. (EM QAP 7.7.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-10	Verify that the level of oversight of contractor performance applies a graded approach to ensure safety-related items and mission critical items are subject to more rigorous methods. (EM QAP 7.7.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-11	Verify that the process is controlled for the following: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services upon delivery or completion. (NQA-1-2008/2009a, Requirement 7, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-12	Prior to award of a contract, verify that the purchaser evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents to include one or more of the following: (a) Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The supplier's history shall reflect current capability. (b) Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated. (c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the supplier's quality assurance program. Prior to the award of the contract, verify that the purchaser resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation. (NQA-1-2008/2009a, Requirement 7, Parts 200 and 300)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-13	If bids are solicited, verify that the bid evaluation include a determination of the supplier's capability to conform to the technical and quality assurance requirements.	**Personnel Contacted:** •	

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	(NQA-1-2008/2009a, Requirement 7, Part 300)	**Documents Reviewed:** • **Discussion:**	
7-14	Verify that controls are implemented to assure that the submittal and evaluation of supplier-generated documents are accomplished in accordance with the procurement document requirements. Note: The controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria. (NQA-1-2008/2009a, Requirement 7, Part 400)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-15	Prior to offering the item or service for acceptance, verify that the supplier has determined that the item or service being furnished complies with the procurement requirements. (NQA-1-2008/2009a, Requirement 7, Part 501)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-16	Where required by code, regulation, or contract requirement, verify that documentary evidence that items conform to procurement requirements is available at the nuclear facility site prior to installation or use. (NQA-1-2008/2009a, Requirement 7, Part 501)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-17	Prior to accepting an item or service from a supplier, verify that the following is provided: a Supplier Certificate of Conformance, source verification, receiving inspection, or post installation test at the nuclear facility site, or a combination of these methods. (NQA-1-2008/2009a, Requirement 7, Part 502)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-18	A Certificate of Conformance shall meet the following minimum requirements: (a) The certificate shall identify the purchased material or equipment, such as by the purchase order number; (b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of specific requirements or by providing, on-site, a copy of the	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment; (c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances; (d) The certificates shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function & position are described in the Purchaser's or Supplier's quality assurance program; (e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program; (f) Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier's or independent inspection or test of items. The Purchaser shall conduct such verification at intervals commensurate with the supplier's past quality performance. (NQA-1-2008/2009a, Requirement 7, Part 503)		
7-19	When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities. Verify that source verification is implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, verify that documented evidence of acceptance is furnished to the receiving destination of the item, to the purchaser, and to the supplier. (NQA-1-2008/2009a, Requirement 7, Part 504)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-20	When receiving inspection is used, verify that purchased items are inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier.	**Personnel Contacted:** • **Documents Reviewed:** •	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	Receiving inspection shall verify by objective evidence such features as configuration; identification; dimensional; physical; and other characteristics; freedom from shipping damage; and cleanliness. Verify that the receipt inspection process is coordinated with the review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection. (NQA-1-2008/2009a, Requirement 7, Part 505)	**Discussion:**	
7-21	When post installation testing is used, post installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier. (NQA-1-2008/2009a, Requirement 7, Part 506)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-22	In cases involving procurement of services only, such as third party inspection; engineering and consulting services; auditing; and installation, repair, overhaul or maintenance work, acceptance of service can be accomplished using any or all of the following methods: (a) Technical verification of data produced; (b) Surveillance and/or audit of the activity; (c) Review of objective evidence for conformance to the procurement document requirements. (NQA-1-2008/2009a, Requirement 7, Part 507)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
7-23	Verify methods for the control and disposition of Supplier non-conformances for items and services that do not meet procurement documentation requirements which include: (a) Evaluation of non-conforming items; (b) Submittal of non-conformance notice to Purchaser by Supplier as directed by the Purchaser. The submittals shall include supplier recommended disposition for use-as-is and repair along with technical justification. Non-conformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition:	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	1. technical or material requirement is violated; 2. requirement in supplier documents, which has been approved by the purchaser, is violated; 3. non-conformance cannot be corrected by continuation of the original manufacturing process or by rework; and 4. the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired; (c) Purchaser disposition of supplier recommendation; and (d) Verification of the implementation of the disposition; maintenance of records of supplier-submitted non-conformances. (NQA-1-2008/2009a, Requirement 7, Part 600)		
7-24	Where the design utilizes commercial grade items, verify that the purchaser utilize the following requirements of an acceptable alternative to other requirements of this section for procuring and accepting items: (a) The commercial grade item is identified in an approved design output document or an alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will met design requirements applicable to both the replaced item and its application; (b) Source evaluation and selection, where determined necessary by the Purchaser based on complexity and importance to safety, shall be in accordance with section 200 of this requirement; (c) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description; (d) One or a combination of the following methods shall be utilized to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance: 1. special tests or inspections or both; 2. commercial grade survey of the supplier; 3. source verification; 4. acceptable supplier/item performance records; and (e) Prior to acceptance of a commercial grade item the Purchaser shall determine that:	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	1. Damage was not sustained during shipment; and 2. The item has satisfied the specified acceptance criteria; and specified documentation, as applicable to the item, was received and is acceptable. (NQA-1-2008/2009a, Requirement 7, Part 701; NQA-2009a, Subpart 2.14)		
7-25	Verify that the following QA requirements are applied to computer software (safety and non-safety software) used for nuclear facility applications: software acquisition method(s) for controlling the acquisition process for software and software service; software engineering method(s) used to manage the software life-cycle activities; application of standards, conventions, and other work practices that support the software life cycle; and controls for support software used to develop, operate, and maintain computer programs. (EM QAP 7.7.1)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
8-1	**Criterion 8 – Performance/Inspection and Acceptance Testing** Verify that the evaluated organization plans and performs oversight or assessment of program implementation to ensure acceptability of work or items that may include: - Inspection/test planning - Inspection/test methods - Inclusion of inspection and test acceptance criteria in work and inspection, test implementing documents - Calibration and control of inspection, measuring and test equipment - Documentation and records (EM QAP 7.8.1 and 7.8.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
8-2	Verify that inspections of items or activities to specified requirements or continued acceptability of items in services are planned and conducted. Verify that periodic inspections or surveillances of structures, systems, or components are planned and executed to assure the continued performance of their required functions. (EM QAP 7.8.2; NQA-1-2009/2009a Requirement 10, Parts 100 and 700)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
8-3	Verify that inspection for acceptance is performed by qualified persons other than those who performed or directly supervised the work being inspected. (NQA-1-2009a Requirement 10, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
8-4	Verify that characteristics to be inspected, methods of inspection, and acceptance criteria are identified during the inspection planning process. (NQA-1-2009a Requirement 10, Part 401)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
8-5	Verify that equipment used for inspections and tests are calibrated and maintained. (EM QAP 7.8 and 7.8.1;NQA-1-2009a Requirement 10, Parts 301 to 304)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
8-6	Verify that status of inspection and test activities are identified either on the item or in documents traceable to the items to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. (NQA-1-2009a Requirement 14, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
9-1	**Criterion 9 – Assessment/Management Assessment** Verify that managers periodically evaluate the performance of their organizations. Assessments shall be scheduled. (EM QAP 7.9.1) (NQA-1 2008/2009a, Requirement 2, Part 100) (NQA-1 2008/2009a, Requirement 18, Part 200)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
9-2	Verify that management assessments include verifying the following: a. roles and responsibilities are known and understood, b. processes and procedures are effectively implemented, c. appropriate measurement systems are in place and functional, d. evidence of continuous improvement is readily available, e. procedures are being complied with, organizational activities are consistent with the mission, and customer requirements and expectations are satisfied. (EM QAP 7.9.1) (NQA-1 2008/2009a, Requirement 18, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
9-3	Verify that managers assess their organization's performance with regards to safety, quality, mission completion, and performance against technical	**Personnel Contacted:** • **Documents Reviewed:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	and financial goals and objectives, and that management consolidates the ISMS and QA validation and declaration activities where possible. (EM QAP 7.9.1) (NQA-1 2008/2009a, Requirement 18, Part 100)	• **Discussion:**	
9-4	Verify that management assessments are performed by personnel knowledgeable in the subject area and trained in assessment techniques. Verify that the manager has significant personal participation in the assessment. (EM QAP 7.9.1) (NQA-1 2008/2009a, Requirement 18, Part 300)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
9-5	Verify that management assessment results are documented and reported to management. (EM QAP 7.9.1) (NQA-1 2008/2009a, Requirement 18, Part 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
9-6	Verify that deficiencies are identified and tracked with corrective actions taken. (EM QAP 7.9.1) (NQA-1 2008/2009a, Requirement 18, Parts 600 and 700)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
9-7	Verify that oversight plans and associated assessment procedures include requirements to: a. document improvement actions b. process lessons learned, as applicable c. provide a copy of the final assessment report so that follow-up improvement actions resulting from the assessment can be entered into an issues tracking system for tracking and a record of the assessment can be established. (EM QAP 7.9.1) (NQA-1 2008/2009a, Requirement 18, Part 301)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
9-8	Verify that management assessment records are maintained. (EM QAP 7.9.1) (NQA-1 2008/2009a, Requirement 18, Part 800)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
10-1	**Criterion 10 - Assessment/Independent Assessment** Verify that a process is established to; a. independently assess and conduct audits of reporting organizations against technical, programmatic, administrative, and quality program requirements; b. ensure their QA programs are assessed to verify compliance and effectiveness of the quality requirements implementation at a frequency such that all elements of the QA program are addressed at least triennially. Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage. (EM QAP 7.10.1) (NQA-1 2008/2009a, Requirement 18, Parts 100 and 200)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-2	Verify that a comprehensive plan for each audit is developed and implemented which identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. (EM QAP 7.10.1) (NQA-1 2008/2009a, Requirement 18, Part 303)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-3	Verify that lead auditors, auditors and technical specialists are technically qualified and knowledgeable in the areas to be assessed, and meet the qualification requirements as specified in NQA-1, 2008/2009a, Requirement 2, Sections 303, 304 and 305. (EM QAP 7.10.1) (NQA-1-2008/2009a, Requirement 2, Parts 303-305) (DOE Order O 414.1D, Attachment 2, 10.c)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-4	Verify that audits are performed in accordance with written procedures or checklists by personnel who are knowledgeable in the subject area and do not have direct responsibility for performing the activities being audited. (EM QAP 7.10.1) (NQA-1 2008/2009a, Requirement 18, Part 100) (DOE O 414.1D, Attachment 2, 10.c)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-5	Verify audit results are documented, reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.	**Personnel Contacted:** •	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	Verify management of the audited organization or activity investigates adverse audit findings, schedules corrective action, including measures to prevent recurrence of significant conditions adverse to quality and notify the appropriate organization in writing of action taken or planned. Verify audit responses are evaluated by or for the audited organization. (EM QAP 7.10, 7.10.1) (NQA-1 2008/2009a, Requirement 18, Parts 100 and 600)	**Documents Reviewed:** • **Discussion:**	
10-6	Verify that elements selected for the independent assessment/audit are evaluated against specified requirements with objective evidence examined to the depth necessary to determine if these elements are being implemented effectively. (EM QAP 7.10) (NQA-1 2008/2009a, Requirement 18, Part 400)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-7	Verify that conditions requiring prompt corrective action are reported immediately to management of the audited organization. (EM QAP 7.10) (NQA-1 2008/2009a, Requirement 18, Part 400)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-8	Verify the independent assessment/audit report is signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. (EM QAP 7.10) (NQA-1 2008/2009a, Requirement 18, Part 500)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-9	Verify that the independent assessment/audit report contents include: a. description of the audit scope. b. identity of auditors and personnel contacted. c. summary of results, including a statement on the effectiveness of the elements audited. d. description of each reported adverse finding (EM QAP 7.10) (NQA-1 2008/2009a, Requirement 18, Part 500)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-10	Verify that a formal root cause analysis is considered based on the complexity of the identified significant issue, and extent of conditions identified.	**Personnel Contacted:** • **Documents Reviewed:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	(EM QAP 7.10.1)	• **Discussion:**	
10-11	Verify follow-up action is taken to assure corrective action is accomplished as scheduled. (EM QAP 7.10.1) (NQA-1 2008/2009a, Requirement 18, Part 700)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
10-12	Verify that audit records include audit plans, audit reports, written replies, and the record of completion of corrective action. (EM QAP 7.10.1) (NQA-1 2008/2009a, Requirement 18, Part 800)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
D-1	**Attachment D: Graded Approach** Items and services may require varying degrees of control and verification to ensure compliance with requirements. Some factors that should be considered in determining appropriate levels of control and verification are: (a) the hazards associated with doing the work or using the results of the work (b) the consequences of malfunction or failure of the item, or inappropriate use of the results of services provided (c) the probability of the occurrence of the postulated consequences (d) the design and fabrication complexity or uniqueness of the item, or difficulty to perform services (e) the need for special controls and oversight of processes, equipment, and performance (f) the degree to which functional compliance can be demonstrated by inspection, test, or performance verification (g) the quality history and degree of standardization of items and services (h) the difficulty of repair, replacement, or replication of the items and services (NQA-1-2008/2009a, PART III, Subpart 3.1 and NONMANDATORY APPENDIX 2A-2502)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
D-2	Verify that the graded approach is described in the QAP.	**Personnel Contacted:** •	

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	(DOE Order 414.1D Section 4.2)	**Documents Reviewed:** • **Discussion:**	
D-3	Verify that the graded approach implements NQA-1 2008/2009a QA criteria as defined in Attachment 2, as well as the requirements in Attachment 3 for all facilities, and for nuclear facilities, the requirements in Attachment 4. Note: This requires that all software meet applicable QA requirements in Attachment 2, using a graded approach. (DOE Order 414.1D Section 4.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
D-3	Verify that the following factors were considered in determining the degrees of control and verification to ensure compliance with requirements: (a) the hazards associated with doing the work or using the results of the work (b) the consequences of malfunction or failure of the item, or inappropriate use of the results of services provided (c) the probability of the occurrence of the postulated consequences (d) the design and fabrication complexity or uniqueness of the item, or difficulty to perform services (e) the need for special controls and oversight of processes, equipment, and performance (f) the degree to which functional compliance can be demonstrated by inspection, test, or performance verification (g) the quality history and degree of standardization of items and services (h) the difficulty of repair, replacement, or replication of the items and services (NQA-1 2008/2009a Part III, Subpart 3.1 Nonmandatory Appendix 2A-2, Paragraph 502)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
D-4	Verify that the graded approach: (a) Describes how the criteria/requirements are met, using the documented graded approach. (b) Flows down the applicable QA requirements and responsibilities throughout all levels of the organization, (c) Implements NQA-1 2008/2009a as the consensus QA standard. (DOE Order 414.1D Section 4.2)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
D-5	Verify that gaps between NQA-1 2008/2009a and DOE Order 414.1D are addressed in the QAP as part of the graded approach.	**Personnel Contacted:** •	

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	(DOE Order 414.1D Section 4.2)	**Documents Reviewed:** • **Discussion:**	
G-1	**Attachment G: Software Quality Assurance** Verify that appropriate requirements of Subpart 2.7 (acquisition, development, operation, maintenance, and retirement) are implemented through the policies, procedures, plans, specifications, or work practices, etc., that provide the framework for software engineering activities (NQA-1-2008/2009a, Subpart 2.7, Section 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-2	Verify the requirements of Subpart 2.7 are used in conjunction with applicable Requirements of Part I when and to the extent specified by the organization invoking the Subpart. (NQA-1-2008/2009a, Subpart 2.7, Section 100)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-3	Verify the scope of software engineering activities include the following elements, as appropriate: (a) Software acquisition method(s) for controlling the acquisition process for software and software services. (b) Software engineering method(s) used to manage the software life-cycle activities. (c) Application of standards, conventions, and other work practices that support the software life cycle. (d) Controls for support software used to develop, operate, and maintain computer programs. (NQA-1-2008/2009a, Subpart 2.7, Section 101)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-4	Verify the appropriate software engineering elements, described in Para. 101 of Subpart 2.7, define the baseline documents that are to be maintained as records, in accordance with Part I, Requirement 17. Although multiple documentation requirements are specified within this Subpart, they can be provided as separate or as combined documents. (NQA-1-2008/2009a, Subpart 2.7, Section 201)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
G-5	Verify the appropriate software engineering elements, described in Para. 101 of Subpart 2.7, define the control points and associated reviews. (NQA-1 2008/2009a, Subpart 2.7, Section 202)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-6	Verify reviews of software ensure compliance with the approved software design requirements. (NQA-1-2008/2009a, Subpart 2.7, Section 202)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-7	Verify the following two required reviews performed: (a) One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification. (b) The other review shall provide assurance of the satisfactory completion of the software development cycle including acceptance testing. This review can be combined with or be part of software design verification. Individual(s) familiar with the design detail and the intended use of the computer program shall be included in the review. (NQA-1-2008/2009a, Subpart 2.7, Section 202)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-8	Verify reviews identify the participants and their specific review responsibilities. (NQA-1-2008/2009a, Subpart 2.7, Section 202)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-9	Verify that documentation of review comments and their disposition is retained until they are incorporated into the updated software. (NQA-1-2008/2009a, Subpart 2.7, Section 202)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-10	When review alone is not adequate to determine if requirements are met, determine if alternate calculations used, or are tests developed and integrated into the appropriate activities of the software development cycle. (NQA-1-2008/2009a, Subpart 2.7, Section 202)	**Personnel Contacted:** • **Documents Reviewed:** •	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
		Discussion:	
G-11	Verify that tests and test results are included in the acceptance testing documentation. (NQA-1-2008/2009a, Subpart 2.7, Section 202)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-12	Verify such tests are subjected to the same criteria as the acceptance tests. (NQA-1-2008/2009a, Subpart 2.7, Section 202)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-13	In addition to the requirements of Part I, Requirement 3, verify software configuration management activities include the following: (a) The appropriate software engineering elements, described in Para. 101 of this Subpart, shall identify when configuration baselines are to be established. Configuration items to be controlled shall include, as appropriate: 1) Documentation (e.g., software design requirements, instructions for computer program use, test plans, and results). 2) Computer program(s) (e.g., source, object, backup files). 3) Support software. (b) The software configuration change control process shall include: (1) Initiation, evaluation, and disposition of a change request. (2) Control and approval of changes prior to implementation. (3) Requirements for retesting and acceptance of the test results. (NQA-1-2008/2009a, Subpart 2.7, Section 203)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-14	Verify that method(s) for documenting, evaluating, and correcting software problems: (a) Describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake). (b) Define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation.	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	(NQA-1-2008/2009a, Subpart 2.7, Section 204)		
G-15	When a problem is determined to be an error, verify that the method selected provides, as appropriate, for: (a) How the error relates to appropriate software engineering elements. (b) How the error impacts past and present use of the computer program. (c) How the corrective action impacts previous development activities. (d) How the users are notified of the identified error, its impact; and how to avoid the error, pending implementation of corrective actions. (NQA-1-2008/2009a, Subpart 2.7, Section 204)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-16	Verify that the problem reporting and corrective action process addresses the appropriate requirements of Part I, Requirement 16. (NQA-1-2008/2009a, Subpart 2.7, Section 204)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-17	Verify that software acquisition include software or software services procured in accordance with Part I, or otherwise acquired for use in activities within the scope of Part I. (NQA-1-2008/2009a, Subpart 2.7, Section 300)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-18	Verify that Part I, Requirements 4 and 7 for items and services are applied to the procurement of software and software services. (NQA-1-2008/2009a, Subpart 2.7, Section 301)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-19	Verify that the Purchaser is responsible for the appropriate requirements of this Subpart upon acceptance of the software or related item (e.g., programmable device). (NQA-1-2008/2009a, Subpart 2.7, Section 301)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
G-20	Verify that procurement documents identify requirements for Supplier's reporting of software errors to the Purchaser and, as appropriate, the Purchaser's reporting of software errors to the Supplier. (NQA-1-2008/2009a, Subpart 2.7, Section 301)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-21	Verify that software that has not been previously approved under a program is consistent with this Standard for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software), evaluated in accordance with the requirements of this Subpart. (NQA-1-2008/2009a, Subpart 2.7, Section 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-22	Verify that software is identified and controlled prior to evaluation. (NQA-1-2008/2009a, Subpart 2.7, Section 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-23	Verify that the evaluation, specified by this section, is performed and documented to determine adequacy to support operation and maintenance and identify the activities to be performed and the documentation that is needed. (NQA-1-2008/2009a, Subpart 2.7, Section 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-24	Verify that this determination is documented and verify that it identify, as a minimum: (a) Capabilities and limitations for intended use. (b) Test plans and test cases required demonstrating the capabilities within the limitations. (c) Instructions for use within the limits of the capabilities. (NQA-1-2008/2009a, Subpart 2.7, Section 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-25	Verify that exceptions from the documentation requirements of this Subpart and the justification for acceptance are documented. (NQA-1-2008/2009a, Subpart 2.7, Section 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
G-26	Verify that the results of the above evaluation and the performance of the actions necessary to accept the software are reviewed and approved. (NQA-1-2008/2009a, Subpart 2.7, Section 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-27	Verify that the resulting documentation and associated computer program(s) establish the current baseline. (NQA-1-2008/2009a, Subpart 2.7, Section 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-28	Verify that revisions to previously baselined software received from organizations are not required to follow this Subpart evaluated in accordance with this section. (NQA-1-2008/2009a, Subpart 2.7, Section 302)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-29	In accordance with requirements of Part I, Requirement 3, verify that software engineering method(s) are documented, and that the selected software engineering method ensures that software life cycle activities are planned and performed in a traceable and orderly manner. (NQA-1-2008/2009a, Subpart 2.7, Section 400)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-30	Verify that software design requirements address technical and software engineering (i.e., Para. 101 of this Subpart) requirements. (NQA-1-2008/2009a, Subpart 2.7, Section 401)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-31	Verify that software design requirements are traceable throughout the software life cycle. (NQA-1-2008/2009a, Subpart 2.7, Section 401)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-32	Verify that software design considers the computer program's operating environment. (NQA-1-2008/2009a, Subpart 2.7, Section 402)	**Personnel Contacted:** • **Documents Reviewed:** •	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
		Discussion:	
G-33	Verify that measures to mitigate the consequences of problems are an integral part of the design, including external and internal abnormal conditions and events that can affect the computer program. (NQA-1-2008/2009a, Subpart 2.7, Section 402)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-34	Verify that software design verification evaluates the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design, and verify that software design is traceable to the software design requirements. (NQA-1-2008/2009a, Subpart 2.7, Section 403)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-35	Verify that software design verification includes review of test results. (NQA-1-2008/2009a, Subpart 2.7, Section 403)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-36	Verify that software design verification is completed prior to approval of the computer program for use. (NQA-1-2008/2009a, Subpart 2.7, Section 403)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-37	Verify that the requirements for the software design verification activity are documented in the software engineering method. (NQA-1-2008/2009a, Subpart 2.7, Section 403)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-38	Verify that the implementation process result in software products such as computer program listings and instructions for computer program use, are reviewed in accordance with para. 202 of this Subpart. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-39	Verify that the acceptance testing activity demonstrates that the computer program adequately and correctly performs all intended functions (i.e.,	**Personnel Contacted:** •	

Environmental Management Quality Assurance Checklist

7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	specified software design requirements) and demonstrate, as appropriate, that the computer program: (a) Properly handles abnormal conditions and events as well as credible failures. (b) Does not perform adverse unintended functions. (c) Does not degrade the system either by itself, or in combination with other functions or configuration items. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Documents Reviewed:** • **Discussion:**	
G-40	Verify that acceptance testing is performed prior to approval of the computer program for use. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-41	Verify that configuration items are under configuration change control prior to starting acceptance testing. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-42	Verify that acceptance testing is planned and performed for all software design requirements, including a comprehensive acceptance test performed in the operating environment prior to use. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-43	Verify that test plans, test cases, and test results are documented, reviewed, and approved prior to use of the computer program in accordance with Part I, Requirement 11. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-44	Verify that observations of unexpected or unintended results are documented and dispositioned prior to test result approval. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
G-45	Verify that acceptance testing of changes to the computer program is subjected to selective retesting to detect unintended adverse effects introduced during the change. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-46	Verify that selective retesting provides assurance that the changes have not caused unintended adverse effects in the computer program, and to verify that a modified system(s) or system component(s) still meets specified software design requirements. (NQA-1-2008/2009a, Subpart 2.7, Section 404)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-47	Verify that after the software is approved for use and installed in the operating environment, is the use of the software controlled in accordance with approved procedures and instructions, including, as appropriate: (a) Application documentation (e.g., application log). (b) Access control specifications. (c) Problem reporting and corrective action. (d) In-use tests. (e) The configuration change control process. (NQA-1-2008/2009a, Subpart 2.7, Section 405)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-48	Verify that the appropriate software engineering elements, as described in para. 101 of this Subpart, identify how changes to the software are controlled, such as: (a) Enhancement requests from the user community. (b) Revisions to software based on software design requirements. (c) Changes to the operating environment. (d) Reported software problems that must be corrected. (NQA-1-2008/2009a, Subpart 2.7, Section 406)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-49	During retirement, verify that support for the software product is terminated, and the routine use of the software is prevented. (NQA-1-2008/2009a, Subpart 2.7, Section 407)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
G-50	As appropriate, verify that the software engineering method, software acquisition method, or both, establishes the need for standards, conventions, and other required work practices to facilitate software life cycle activities (e.g., software design and implementation activities). (NQA-1-2008/2009a, Subpart 2.7, Section 500)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-51	Verify that standards, conventions, and other required work practices are documented. (NQA-1-2008/2009a, Subpart 2.7, Section 500)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-52	As appropriate, verify that the software engineering method, software acquisition method, or both establish the need for software tools (NQA-1-2008/2009a, Subpart 2.7, Section 600)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-53	Verify that software tools that affect the performance of the software are evaluated, reviewed, tested, and accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. (NQA-1-2008/2009a, Subpart 2.7, Section 601)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-54	In cases involving modifications of software products using the software tools, verify that the configuration of the support software associated with that modification is managed. (NQA-1-2008/2009a, Subpart 2.7, Section 601)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-55	Verify that changes to the software tool are evaluated for impact on the software product to determine the level of reviews and retesting that will be required. (NQA-1-2008/2009a, Subpart 2.7, Section 601)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-56	Verify that system software is evaluated, reviewed, tested, and accepted for use as part of the software development cycle of a new or revised software product. (NQA-1-2008/2009a, Subpart 2.7, Section 602)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
G-57	Verify that system software is placed under configuration change control. (NQA-1-2008/2009a, Subpart 2.7, Section 602)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
G-58	Verify that changes to the system software are evaluated for impact on the software product to determine the level of reviews and retesting that will be required. (NQA-1-2008/2009a, Subpart 2.7, Section 602)	**Personnel Contacted:** • **Documents Reviewed:** • **Discussion:**	
H-1	**Attachment H: Model Development, Use, and Validation** Verify that model development and approaches to validation are planned, controlled, and documented. Verify that planning for model validation identifies the validation methods and the validation criteria used. If model validation activities *are* completed after documentation of the model (i.e., using new confirmation test data gathered in the field or laboratory), verify that these activities are described in the work planning document. (EM QAP Attachment H)		
H-2	Verify that model documentation includes: • Model objective (intended use) and definition. • Description of conceptual model and scientific basis, as well as alternatives for the selected conceptual model, including rationale for not selecting alternatives. • Results of literature searches and applicable background information. • Inputs and their sources. • Identification of and rationale for assumptions are made to develop or apply the model, including model idealizations, as well as those assumptions that support the input to the model and impact model results. • Mathematical and numerical methods and software used, including governing equations, formulas, and algorithms, and their scientific and mathematical bases. • Identification of any associated software used, computer calculations performed, and basis to permit traceability of inputs and outputs.		

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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results
	• Initial/boundary conditions. • Limitations (i.e., data available for model development, valid ranges of model application, spatial and temporal scaling). • Uncertainties (e.g., conceptual model, mathematical model, process model, abstraction model, system model, parameters) and how they affect the model. • Identification of the originator, reviewer, and approver. (EM QAP Attachment H)		
H-3	Verify that the intended use and importance of the model is used to determine the appropriate level of confidence for a model (i.e, models of system components most relied upon are validated with the highest levels of confidence to the extent practical). (EM QAP Attachment H)		
H-4	Verify that the criteria for model validation are clearly established to: • Determine the adequacy of the scientific basis for the model is consistent with the model application and justified in the model documentation. • Demonstrate that the model is sufficiently accurate for its intended use. • Define the importance of the model for assessing repository system performance. • Describe the relative level of confidence for the model. • Define the supporting information needed to substantiate validation. Verify methods used to validate from conceptual model to mathematical model to process model to abstraction model to system model: • Describe the relative level of confidence for the model. • Define the supporting information needed to substantiate validation. • Corroboration of model results. • Peer review (Subsection 2.2.8) or independent technical review (Subsection 6.2.3). • Performance confirmation studies using validation test model predictions prior to comparison with field or laboratory data. • Comparison of model results with other results obtained from the implementation of an alternative validated model. (EM QAP Attachment H)		